DEPARTMENT OF HEALTH AND HUMAN SERVICES

94953d

Food and Drug Administration
Seattle District
Pacific Region
22201 23rd Drive SE
Bothell, WA 98021-4421

Telephone: 425-486-8788
FAX: 425-483-4996

September 2, 2004

VIA CERTIFIED MAIL
RETURN RECEIPT REQUESTED

In reply refer to Warning Letter SEA 04-44

Kristy B. Bold, President
Nelson Crab, Incorporated
3088 Kindred Avenue
Tokeland, Washington 98590

WARNING LETTER

Dear Ms. Bold:

On June 8, 9, and 11, 2004, we inspected your firm located at 3088 Kindred Avenue Tokeland, Washington. We found that you have serious deviations from the seafood Hazard Analysis and Critical Control Points (HACCP) Regulation, Title 21, Code of Federal Regulations, Part 123 (21 CFR 123). In accordance with 21 CFR 123.6(g), failure of a processor to have and implement a HACCP plan that complies with this section or otherwise operate in accordance with the requirements of this part, renders the fishery products adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. 342 (a)(4). Accordingly your vacuum packaged cooked Dungeness crab meat and your shad are adulterated in that they have been prepared, packed, or held under insanitary conditions whereby they may have become contaminated with filth, or whereby they may have been rendered injurious to health. You can find this Act, the Seafood HACCP regulation, and the FDA Fish and Fisheries Products Hazards and Controls Guidance through links in FDA's homepage at www.fda.gov.

The deviations were as follows:

1. **You must have a HACCP plan that, at a minimum, lists the critical control points, to comply with 21 CFR 123.6 (a) and (c) (2). A critical control point is defined in 21 CFR Part 123.3(b) as a "point, step, or procedure in a food process at which control can be applied and a food safety hazard can as a result be prevented, eliminated, or reduced to acceptable levels." However, your firm's HACCP plan for cooked Dungeness crab in vacuum-sealed containers does not list appropriate**

critical control points to adequately control the food safety hazard of *Clostridium botulinum* growth toxin formation. In order to ensure continuous temperature monitoring, FDA recommends that firms use time/temperature indicators (TTIs,) affixing one to each container. Maintaining strict temperature control at 38°F or below for each container throughout distribution, including all handling, storing, shipping, etc. beginning from packing to consumption (or breaking of the vacuum seal) is necessary for products such as yours that are packed under reduced or modified atmospheric conditions.

Please note that information regarding the control of *Clostridium botulinum* in vacuum-packaged and reduced oxygen packaged seafood products can be found in FDA's Fish and Fisheries Products and Hazards Guidance: Third Edition, Chapter 13.

2. You must have a HACCP plan that, at a minimum, lists the critical limits that must be met, to comply with 21 CFR 123.6 (c) (3). A critical limit is defined in 21 CFR Part 123.3 (c) as "the maximum or minimum value to which a physical, biological, or chemical parameter must be controlled at a critical control point to prevent, eliminate, or reduce to an acceptable level the occurrence of the identified food safety hazard. However, your firm's HACCP plan for cooked Dungeness crab lists critical limits at the following critical control points that are not adequate to control the following hazards:

   a. Your firm's HACCP plan for cooked Dungeness crab does not list a critical limit for the time at the "Cook" critical control point. When you choose to monitor the cooking temperature you need to list a corresponding time period that the product is exposed to at that temperature.

      If, however, you are intending to monitor end point internal product temperature, you need to revise your plan accordingly. Our investigator discussed this approach with you and NFPA's recommendation that adequacy of the cook be established through a scientific study.

   b. Your firm's HACCP plan for cooked Dungeness crab does not list adequate critical limits at the "Cooling" critical control point to control the hazard of pathogen growth and toxin production. FDA recommends a two part critical limit for cooling. Cooked product should be cooled to below 70°F within 2 hours of initial handling (i.e., picking) and cooled to 40°F within an additional 2 hours. Your cooling process appears to continue throughout the picking and packing process and your product is significantly handled before it is completely cooled. Therefore, you should monitor the time and temperature of the crabmeat from exit of the cooling tank through to final packaging and placing on ice.

c. In addition, your firm's HACCP plan for fresh shad lists critical limits at the "Receiving" critical control point that are not adequate to control histamine. Your plan indicates that you act as a primary processor receiving the shad directly from the harvest vessels and that you collect harvest vessel records. These records should include information associated with method of capture, date/time of landing, air/water temperatures, method of cooling, time cooling began, storage controls onboard the boat and any other factors as needed. Please refer to Chapter 7 of FDA's Fish and Fisheries Products Hazards and Controls Guidance: Third Edition for additional information on controlling the hazard of histamine.

3. You must implement the monitoring procedures that you have listed in your HACCP plan, to comply with 21 CFR 123.6(b). However,

   a. Your firm did not follow the listed monitoring procedures and frequency of monitoring the time the product is exposed to temperatures above 40° F at the "Cooling" critical control point in your HACCP plan for cooked Dungeness crab to control pathogen growth and toxin formation. Our investigator noted that the "Cooling" critical control point is not being monitored to ensure that the time/temperature critical limits are being met. You must adequately implement the monitoring and record keeping procedures for the critical limits listed in your plan.

   b. Your firm did not follow your monitoring procedures and frequency as listed your plan for cooked Dungeness crab at the "Storage Vacuum-Packaged Products" critical control point to control the hazard of pathogen growth and toxin formation. Your plan lists that you will monitor storage temperature continuously. Instead you actually monitor the presence of ice.

   c. Your firm failed to continuously monitor the exposure temperatures at your "Cook" critical control point. If you choose to monitor a cooking temperature, rather than visually monitoring a rolling boil you should use a continuous time/temperature data recorder.

4. You must implement the record keeping system listed in your HACCP plans to comply with 21 CFR 123.6(b). However, your firm did not record monitoring observations at the following critical control points to control pathogen growth and toxin formation in your HACCP plan for cooked Dungeness crab and histamine in your HACCP plan for shad.

   a. At the "Storage (Fresh) Air-packaged Products" critical control point in your HACCP plan for cooked Dungeness crab you list an "Icing Log" will be maintained, however your firm failed to maintain this record

documenting the monitoring observations for adequacy of ice covering the products.

b. At the "Storage" critical control point in your HACCP plan for shad you list that a "Storage Record" will be maintained to monitor the adequacy of ice, however your firm failed to have a record documenting monitoring of the adequacy of the ice.

5. Since you chose to include corrective actions in your HACCP plan, your described corrective actions must be appropriate, to comply with 21 CFR 123.7(b). However, the corrective actions listed at the "Cook", "Cooling" and "Storage" critical control points in your plan for cooked Dungeness crab are not adequate because they do not address the cause of the deviations. As part of a HACCP program, FDA expects you to determine how a deviation occurred and take steps to prevent its re-occurrence.

6. You must adequately monitor sanitation conditions and practices during processing, to comply with 21 CFR 123.11(b). However, your firm did not monitor the following areas of sanitation with sufficient frequency to ensure control as evidenced by,

   a. Prevention of cross-contamination from insanitary objects to food, food packaging material, and other food contact surfaces, including workers touching insanitary objects and then handling the cooked crabmeat without sanitizing their hands.

   b. Protection of food, food packaging material, and food contact surfaces from adulteration with lubricants, fuel, pesticides, cleaning compounds, sanitizing agents, condensate, and other chemical, physical, and biological contaminants, as evidenced by a worker placing two filled, open cans of crabmeat on a metal stand, next to a bottle of dishwashing liquid.

   c. Condition and cleanliness of food contact surface, as evidenced by
      i. Cooked-on greenish residue was present on the surfaces of the crab cooker/cooler's metal mesh conveyor.
      ii. A black substance present on the white UHMW plastic conveyor rotators for the crab cooker/cooler's metal mesh conveyor.
      iii. A black mold-like substance present on strip curtains at the exit of the water-cooling unit between the crab cooker's exit and the cooler's entrance.
      iv. A black substance and rust present on the outer and inner surfaces of a vertical PVC water pipe used to fill the crab cooker with water. The pipe was dripping water into the crab-cooking tank throughout processing.

v. **A black substance and rust present on the outer and inner surfaces of two small horizontal perforated PVC pipes used to continually add water to the crab-cooling tank.**
vi. **Black residue present on the handle and the inner surfaces of a small white pitcher used to add water to 5-lb. cans of crabmeat as they are filled.**
~~vii.~~ **The use of packaging materials (metal cans) that were not sanitized prior to filling.**

d. **Exclusion pests from the food plant, as evidenced by**
   i. **Seven flies noted flying through the crabmeat production area.**
   ii. **Three small insects, a live weevil-like insect and two dead gnat-like insects, were noted in the bottoms of 5-lb. metal cans on the crabmeat-packing table.**

In addition, Albacore tuna, which is a product that you handle, also poses a hazard for histamine. We suggest you conduct a hazard analysis to determine if your firm is responsible for control of the histamine hazard. For more information on control strategies associated with scombrotoxin forming species, please refer to Chapter 7 of FDA's Fish and Fisheries Products Hazards and Control Guidance: Third Edition.

Also be advised that you must fully document, in records, all corrective actions taken, in order to comply with 21 CFR 123.7(d). However, you did not appear to document that a corrective action was taken when you deviated from your critical limit of [redacted]°F at the "Receiving" critical control point in your HACCP plan for shad. Your plan lists that you will reject the shipment if [redacted]F is exceeded. Our investigator collected a bill of lading dated June 19, 2003, for totes of shad where the receiving temperature is recorded as 58°F. In addition, our investigator collected a receiving record showing that your firm received a shipment of shad on June 20, 2003, and sampled 12 fish for temperature. Seven of the 12 fish had internal temperatures exceeding [redacted] F. There are no additional comments or records associated with these entries to indicate their final disposition

We may take further action if you do not promptly correct these violations. For instance, we may take further action to seize your product(s) and/or enjoin your firm from operating.

Please respond in writing within three (3) weeks from your receipt of this letter. Your response should outline the specific things you are doing to correct these deviations. You may wish to include in your response documentation such as your completed HACCP plan or other useful information that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, we expect that

you will explain the reason for your delay and state when you will correct any remaining deviations.

This letter may not list all the deviations at your facility. You are responsible for ensuring that your processing plant operates in compliance with the Act, the Seafood HACCP regulations, and the Current Good Manufacturing Practice regulations (21 CFR Part 110). You also have a responsibility to use procedures to prevent further violations of the Act and all applicable regulations.

Please send your reply to the Food and Drug Administration, Attention: Michael J. Donovan, Compliance Officer, 22201 23rd Drive SE, Bothell, Washington 98021. If you have questions regarding any issue in this letter, please contact Mr. Donovan at (425) 483-4906.

Sincerely,

Charles M. Breen
District Director

Enclosures:
Form FDA 483

cc: WSDA with disclosure statement